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SIGA TECHNOLOGIES INC
Form 424B3
January 26, 2005

PROSPECTUS

Filed pursuant to Rule 424(b)(3)
Registration No. 333-120742

1,000,000 SHARES

SIGA TECHNOLOGIES, INC.

COMMON STOCK

Shares of common stock of SIGA Technologies, Inc. are being offered by this prospectus. The shares will be sold from time to time by the selling stockholders named in this prospectus. The prices at which such selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any proceeds from the sale of shares of common stock by the selling stockholders. Our shares are traded on the Nasdaq SmallCap Market under the symbol "SIGA." Our principal executive offices are located at 420 Lexington Avenue, Suite 601, New York, New York 10170. Our telephone number is (212) 672-9100.

Investing in the shares involves a high degree of risk. For more information, please see "Risk Factors" beginning on page 4.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 14, 2005

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ABOUT SIGA TECHNOLOGIES, INC.

We are a technology company, whose primary focus is on biopharmaceutical product development. Our focus is on (1) novel antibiotics and antivirals for biological warfare defense and gram-positive and gram-negative bacterial infections; (2) mucosal vaccines for biodefense targets, strep throat and sexually transmitted diseases, and (3) commensal bacteria for the delivery of vaccines. As of the date of this prospectus, none of our products have been approved for commercial sale and, therefore, we have not generated any revenues from the commercial sale of our products. To date, we have relied on a combination of private financings, grants and collaboration agreements to fund our operations.

Biological Warfare Defense

We are developing a host of technologies to aid in biological warfare defense. These technologies include anti-smallpox drugs, and treatments for toxins and infections that may be used in an act of terrorism.

The FDA has amended its regulations to make it easier to approve biological warfare defense products. In addition, the U.S. federal government increased the amount of money committed to support research in this area.

In August 2004, we acquired certain government grants and two early stage antiviral programs, Smallpox and Arenavirus, targeting certain agents of biological warfare from ViroPharma Incorporated. As part of the transaction, we were awarded Phase I and II SBIR grants from the National Institute of Health, or "NIH," totaling approximately \$12 million, which will be received over the next two years, for the development of drugs for the treatment of Smallpox and Arenavirus as noted above.

Anti-Infectives

Our anti-infectives research targets infections that are acquired in hospitals and drug-resistant bacteria. Our aim is to block the ability of bacteria to attach and colonize human tissue and to cut off infection at the first stage in the process. We are developing technologies to treat both major classes of bacteria--gram-positive and gram-negative.

Gram-Positive Antibiotic Technology

We are developing an antibiotic technology based on the research of our founding scientists which makes it more difficult for gram-positive bacteria to attach to human tissue. Our scientists found that most gram-positive bacteria utilize a particular enzyme, a protease, to attach to and colonize human tissue. Our strategy is to develop antibiotics that inhibit the generation of protease. In 1997, we entered into a collaborative research and license agreement with the Wyeth-Ayerst Laboratories Division of American Home Products Corporation to identify and develop protease inhibitors. Wyeth has completed high throughput screening of compound libraries and is currently evaluating lead compounds. In the first quarter of 2001, we received a milestone payment from Wyeth at the

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beginning of screening for protease inhibitors. We also licensed technology from the University of California at Los Angeles which may be incorporated into our development of products for Wyeth.

Gram-Negative Antibiotic Technology

We are developing a technology to inhibit the ability of gram-negative bacteria to attach to human tissue. Gram-negative bacteria utilize structures called pili to adhere to human tissue. We believe that inhibiting the assembly of pili should effectively inhibit diseases caused by these structures. In July 1999 and August 2000 we were awarded research grants from the NIH, to support our development efforts in this area. We entered into agreements with Med Immune Inc., Astra AB and Washington University, pursuant to which we acquired rights to certain gram-negative antibiotic targets, products, screens and services developed at Washington University. In February 2000, we ended our collaborative relationship with

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Washington University on this technology, but we are still developing the technology which we acquired in the initial agreements.

Broad-Spectrum Antibiotic Technology

We have identified a stress response enzyme, DegP, which is conserved in both gram-positive and gram-negative bacteria. It appears to enable bacteria to deal with external stress factors such as temperature or oxygen radicals. Our scientists have found that organisms lacking a functional DegP proteinase have a decreased ability to cause disease. We believe that DegP represents a true broad-spectrum anti-infective development target. This line of research is still too early to make accurate assessments of its development possibilities.

Mucosal Vaccines

We are developing vaccines and a delivery system for these vaccines. We are currently developing mucosal vaccines for strep throat and for sexually transmitted diseases, or "STDs." A mucosal vaccine is a vaccine that activates the immune system at the mucus-lined surfaces of the body--the mouth, the nose, the lungs and the gastrointestinal and urogenital tracts--the sites of entry for most infectious agents. The system we are developing to deliver these mucosal vaccines uses genetically engineered commensal bacteria. Commensal bacteria are harmless bacteria that naturally inhabit the body's surfaces, particularly the mucus-lined areas.

Strep Throat Vaccine Candidate

We are developing with technology we licensed from The Rockefeller University, or "Rockefeller," a mucosal vaccine for strep throat. This vaccine has demonstrated an ability to colonize and induce both a local and systemic immune response in mice and rabbits. We are collaborating with the NIH and the University of Maryland Center for Vaccine Development on the clinical development of this vaccine candidate. In December 1997, we, in cooperation with the NIH, filed an Investigational New Drug Application with the United States Food and Drug Administration, or "FDA." In September 1999, the NIH awarded us a research grant to help support the research cost of our strep program.

The first stage of clinical trials was completed at the University of Maryland in 2000. The study showed the delivery system to be well-tolerated and that the commensal bacteria was spontaneously or easily eradicated. A second clinical trial of the commensal delivery system without the strep throat vaccine

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technology was initiated in 2000 at the University of Maryland. This trial was completed in January 2002 and the results corroborated the conclusions of the earlier study regarding tolerance and eradication. We are currently performing experiments to test the vaccine formulation prior to initiating Phase I human trials with the vaccine.

Sexually Transmitted Disease Vaccine Candidates

We are developing a mucosal vaccine for STDs utilizing technology we licensed from Oregon State University and Washington University. We are primarily focused on developing a vaccine for chlamydia, the most common form of STD, and Neisseria, the agent which causes gonorrhea. As both of these STDs enter people via mucus-lined surfaces of the body, we believe that a mucosal vaccine will be a more effective delivery method than a traditional vaccine. In February 2000, we entered into an agreement with the Ross Products Division of Abbott Laboratories under which Ross provided us with funding for development of an STD vaccine. The research program was completed in late 2001. The agreement was extended through the first quarter of 2003 to permit an additional set of experiments to be conducted, one of which has not been conducted as of the date of this prospectus. The parties to the agreement are currently considering whether to proceed with the remaining experiment.

Surface Protein Expression System

We are developing a technology to overproduce many bacterial and human proteins. The current methods of overproducing such proteins have faced difficulties in purifying the proteins. By applying their

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knowledge of gram-positive bacterial protein expression, our scientists have developed our surface protein expression system, or "SPEX." Our scientists believe that SPEX eases the protein purification, as well as increasing the likelihood that the secreted proteins will be folded properly. We have recently used the SPEX system to obtain large quantities of a pure protein antigen in preclinical studies. We have commenced a program to transfer the method from a laboratory scale environment to a commercial production facility. Our business strategy is to license this technology on a non-exclusive basis for a broad range of applications.

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RISK FACTORS

Investing in our common stock involves a high degree of risk, and you should be able to bear losing your entire investment. You should carefully consider the risks presented by the following factors.

We have incurred operating losses since our inception and expect to incur net losses and negative cash flow for the foreseeable future.

We incurred net losses of approximately \$6.3 million for the nine months ended September 30, 2004, \$5.3 million and approximately \$3.3 million for the years ended December 31, 2003 and 2002, respectively. As of September 30, 2004, December 31, 2003 and December 31, 2002, our accumulated deficit was approximately \$41.1 million, \$34.8 million and \$29.5 million, respectively. We expect to continue to incur significant operating expenditures. We will need to generate significant revenues to achieve and maintain profitability.

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We cannot guarantee that we will achieve sufficient revenues for profitability. Even if we do achieve profitability, we cannot guarantee that we can sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow slower than we anticipate, or if operating expenses exceed our expectations or cannot be adjusted accordingly, then our business, results of operations and financial condition will be materially and adversely affected. Because our strategy includes acquisitions of other businesses, acquisition expenses and any cash used to make these acquisitions will reduce our available cash.

Our business will suffer if we are unable to raise additional equity funding.

We continue to be dependent on our ability to raise money in the equity markets. There is no guarantee that we will continue to be successful in raising such funds. If we are unable to raise additional equity funds, we may be forced to discontinue or cease certain operations. We currently have sufficient operating capital to finance our operations at least through the year ending December 31, 2005. Our annual operating needs vary from year to year depending upon the amount of revenue generated through grants and licenses and the amount of projects we undertake, as well as the amount of resources we expend, in connection with acquisitions all of which may materially differ from year to year and may adversely affect our business.

Most of our immediately foreseeable future revenues are contingent upon government grants and contracts, collaborative and license agreements and we may not achieve sufficient revenues from these agreements to attain profitability.

Until and unless we successfully make a product, our ability to generate revenues will largely depend on our ability to procure governments grants and contracts, enter into additional collaborative and license agreements with third parties and maintain the agreements we currently have in place. Substantially all of our revenues for the nine months ended September 30, 2004 and the years ended December 31, 2003 and 2002, respectively, were derived from revenues related to grants, contracts and license agreements. We will receive little or no revenues under our collaborative agreements if our collaborators' research, development or marketing efforts are unsuccessful, or if our agreements are terminated early. Additionally, if we do not enter into new collaborative agreements, we will not receive future revenues from new sources. Our future revenue is substantially dependent on the continuing revenue from grants from the NIH received in August of 2004 totaling approximately \$12 million over a two-year period and contract work being performed for the U.S. Army which expires at the end of December 2007. These agreements are for specific work to be performed under the agreements and could only be canceled by the other party thereto for non-performance by the other party thereto.

Several factors will affect our future receipt of revenues from collaborative arrangements, including the amount of time and effort expended by our collaborators, the timing of the identification of useful drug targets and the timing of the discovery and development of drug candidates. Under our existing agreements, we may not earn significant milestone payments until our collaborators have advanced products into clinical testing, which may not occur for many years, if at all.

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We have material agreements with the following collaborators:

- o The Rockefeller University. The term of our agreement with Rockefeller is for the duration of the patents and a number of

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pending patents. As we do not currently know when any patents pending or future patents will expire, we cannot at this time definitively determine the term of this agreement. The agreement can be terminated earlier if we are in breach of the provisions of the agreement and do not cure the breach in the allowed cure period. We are current in all obligations under the contract.

- o Wyeth. Our license agreement expires on the earlier of June 30, 2007, or the last to expire patent that we have sub-licensed to them. Wyeth has the right to terminate the agreement on 90 days written notice. If terminated, all rights granted to Wyeth will revert to us, except for any compound identified by Wyeth prior to the date of termination and subject to the milestones and royalty obligations of the agreement.
- o National Institutes of Health. Under our collaborative agreement with the NIH, it is required to conduct and pay for the clinical trials of our strep vaccine product through phase II human trials. The NIH can terminate the agreement on 60 days written notice. If terminated, we receive copies of all data, reports and other information related to the trials. If terminated, we would have to find another source of funds to continue to conduct the trials. We are a party to grants awarded in August of 2004 for a total of approximately \$12 million to be paid over a two-year period. We were party to another collaborative agreement with the NIH under which we received a grant for approximately \$865,000. The term of this agreement expired in May 2004.
- o Washington University. We have licensed certain technology from Washington under a non-exclusive license agreement. The term of our agreement with Washington is for the duration of the patents and a number of pending patents. As we do not currently know when any patents pending or future patents will expire, we cannot at this time definitively determine the term of this agreement. The agreement cannot be terminated unless we fail to pay our share of the joint patent costs for the technology licensed. We have currently met all our obligations under this agreement.
- o Regents of the University of California. We have licensed certain technology from Regents under an exclusive license agreement. We are required to pay minimum royalties under this agreement. This agreement is related to our agreement with Wyeth and expires at the same time as that agreement. It can be cancelled earlier if we default on our obligations or if Wyeth cancels its agreement with SIGA and we are not able to find a replacement for Wyeth. We have currently met all our obligations under this agreement.
- o TransTech Pharma, Inc. Under our collaborative agreement with TransTech Pharma, a related party, TransTech Pharma is required to collaborate with us on the discovery, optimization and development of lead compounds to therapeutic agents. We and TransTech Pharma have agreed to share the costs of development and revenues generated from licensing and profits from any commercialized products sales. The agreement will be in effect until terminated by the parties or upon cessation of research or sales of all products developed under the agreement. We are current in all obligations under this agreement.

Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.

The volatile price of our stock makes it difficult for investors to

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predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

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- o publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- o delay or failure in initiating, completing or analyzing pre-clinical or clinical trials or the unsatisfactory design or results of these trials;
- o achievement or rejection of regulatory approvals by our competitors or us;
- o announcements of technological innovations or new commercial products by our competitors or us;
- o developments concerning proprietary rights, including patents;
- o developments concerning our collaborations;
- o regulatory developments in the United States and foreign countries;
- o economic or other crises and other external factors;
- o period-to-period fluctuations in our revenues and other results of operations;
- o changes in financial estimates by securities analysts; and
- o sales of our common stock.

Additionally, because there is not a high volume of trading in our stock, any information about SIGA in the media may result in significant volatility in our stock price.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

The following table presents the high and low bid range of our stock for the past eight quarters.

| Bid Range | | |
|---------------------|--------|--------|
| 2002 | High | Low |
| ----- | ----- | ----- |
| Fourth Quarter..... | \$2.15 | \$0.65 |
| | | |
| 2003 | High | Low |
| ----- | ----- | ----- |
| First Quarter..... | \$1.49 | \$1.02 |

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| | | |
|---------------------|--------|--------|
| Second Quarter..... | \$1.91 | \$1.09 |
| Third Quarter..... | \$2.13 | \$1.61 |
| Fourth Quarter..... | \$2.60 | \$1.80 |
| 2004 | | |
| | High | Low |
| First Quarter..... | \$2.82 | \$1.83 |
| Second Quarter..... | \$2.12 | \$1.25 |
| Third Quarter..... | \$1.75 | \$1.00 |

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We are in various stages of product development and there can be no assurance of successful commercialization.

In general, our research and development programs are at an early stage of development. The strep vaccine program is in Phase I clinical trials. All other programs are in the pre-clinical stage of development. Our biological warfare defense products do not need human clinical trials for approval by the FDA. We will need to perform two animal models and provide safety data for a product to be approved. Our other products will be subject to the approval guidelines under FDA regulatory requirements which include a number of phases of testing in humans.

The FDA has not approved any of our biopharmaceutical product candidates. Any drug candidates developed by us will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercial sale. We cannot be sure our approach to drug discovery will be effective or will result in the development of any drug. We cannot expect that any drugs resulting from our research and development efforts will be commercially available for many years, if at all.

We have limited experience in conducting pre-clinical testing and clinical trials. Even if we receive initially positive pre-clinical or clinical results, such results do not mean that similar results will be obtained in the later stages of drug development, such as additional pre-clinical testing or human clinical trials. All of our potential drug candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that none of our drug candidates will or can:

- o be safe, non-toxic and effective;
- o otherwise meet applicable regulatory standards;
- o receive the necessary regulatory approvals;
- o develop into commercially viable drugs;
- o be manufactured or produced economically and on a large scale;
- o be successfully marketed;
- o be reimbursed by government and private insurers; and
- o achieve customer acceptance.

In addition, third parties may preclude us from marketing our drugs through enforcement of their proprietary rights, or third parties may succeed in marketing equivalent or superior drug products. Our failure to develop safe, commercially viable drugs would have a material adverse effect on our business,

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financial condition and results of operations.

We may face limitations on our ability to attract suitable acquisition opportunities or to integrate additional acquired businesses and the failure to consummate an acquisition may significantly drain our resources.

Our ability to make acquisitions will depend in part on the relative attractiveness of shares of our common stock as consideration for potential acquisition candidates. This attractiveness may depend largely on the relative market price, our ability to register common stock and capital appreciation prospects of our common stock. Failure to make an acquisition will limit our ability to grow, but will not be central to our continued existence. Costs associated with failed acquisitions, may result in significant operating costs that may need to be financed from operations or from additional equity capital.

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We may not be able to consummate potential acquisitions or an acquisition may not enhance our business or may decrease rather than increase our earnings.

In the future, we may issue additional securities in connection with one or more acquisitions, which may dilute our existing shareholders. Future acquisitions could also divert substantial management time and result in short term reductions in earnings or special transaction or other charges. In addition, we cannot guarantee that we will be able to successfully integrate the businesses that we may acquire into our existing business. Our shareholders may not have the opportunity to review, vote on or evaluate future acquisitions.

The biopharmaceutical market in which we compete and will compete is highly competitive.

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. There also are many companies, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these companies have substantially greater financial, technical, research and development, and human resources than us. Competitors may develop products or other technologies that are more effective than any that are being developed by us or may obtain FDA approval for products more rapidly than us. If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have no experience. Many of these companies also have manufacturing facilities and established marketing capabilities that would enable such companies to market competing products through existing channels of distribution. Two companies with similar profiles are VaxGen, Inc., which is developing vaccines against anthrax, Smallpox and HIV/AIDS; and Avant Immunotherapeutics, Inc., which has vaccine programs for agents of biological warfare.

Because we must obtain regulatory clearance to test and market our products in the United States, we cannot predict whether or when we will be permitted to commercialize our products.

A pharmaceutical product cannot be marketed in the U.S. until it has completed rigorous pre-clinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Pharmaceutical products typically take many years to satisfy regulatory requirements and require the expenditure of substantial resources depending on the type, complexity and

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novelty of the product.

Before commencing clinical trials in humans, we must submit and receive clearance from the FDA by means of an Investigational New Drug application. Institutional review boards and the FDA oversee clinical trials and such trials:

- o must be conducted in conformance with the FDA's good laboratory practice regulations;
- o must meet requirements for institutional review board oversight;
- o must meet requirements for informed consent;
- o must meet requirements for good clinical and manufacturing practices;
- o are subject to continuing FDA oversight;
- o may require large numbers of test subjects; and
- o may be suspended by us or the FDA at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the Investigational New Drug application or the conduct of these trials.

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Before receiving FDA clearance to market a product, we must demonstrate that the product is safe and effective on the patient population that will be treated. Data we obtain from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory clearances. Additionally, we have limited experience in conducting and managing the clinical trials and manufacturing processes necessary to obtain regulatory clearance.

If regulatory clearance of a product is granted, this clearance will be limited only to those states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious. We cannot ensure that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing clearance.

If our technologies or those of our collaborators are alleged or found to infringe the patents or proprietary rights of others, we may be sued or have to license those rights from others on unfavorable terms.

Our commercial success will depend significantly on our ability to operate without infringing the patents and proprietary rights of third parties. Our technologies, along with our licensors' and our collaborators' technologies, may infringe the patents or proprietary rights of others. If there is an adverse outcome in litigation or an interference to determine priority or other proceeding in a court or patent office, then we, or our collaborators and licensors, could be subjected to significant liabilities, required to license disputed rights from or to other parties and/or required to cease using a technology necessary to carry out research, development and commercialization. At present we are unaware of any or potential infringement claims against our patent portfolio.

The costs to establish the validity of patents, to defend against patent infringement claims of others and to assert infringement claims against others

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can be expensive and time consuming, even if the outcome is favorable. An outcome of any patent prosecution or litigation that is unfavorable to us or one of our licensors or collaborators may have a material adverse effect on us. We could incur substantial costs if we are required to defend ourselves in patent suits brought by third parties, if we participate in patent suits brought against or initiated by our licensors or collaborators or if we initiate such suits. We may not have sufficient funds or resources in the event of litigation. Additionally, we may not prevail in any such action.

Any conflicts resulting from third-party patent applications and patents could significantly reduce the coverage of the patents owned, optioned by or licensed to us or our collaborators and limit our ability or that of our collaborators to obtain meaningful patent protection. If patents are issued to third parties that contain competitive or conflicting claims, we, our licensors or our collaborators may be legally prohibited from researching, developing or commercializing of potential products or be required to obtain licenses to these patents or to develop or obtain alternative technology. We, our licensors and/or our collaborators may be legally prohibited from using patented technology, may not be able to obtain any license to the patents and technologies of third parties on acceptable terms, if at all, or may not be able to obtain or develop alternative technologies.

In addition, like many biopharmaceutical companies, we may from time to time hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. We and/or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations.

Our ability to compete may decrease if we do not adequately protect our intellectual property rights.

Our commercial success will depend in part on our and our collaborators' ability to obtain and maintain patent protection for our proprietary technologies, drug targets and potential products and to effectively preserve our trade secrets. Because of the substantial length of time and expense associated with bringing potential products through the development and regulatory clearance processes to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of

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claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the type and breadth of claims allowed in these patents.

We have licensed the rights to seven issued U.S. patents and three issued European patents. These patents have varying lives and they are related to the technology licensed from Rockefeller University for the Strep and Gram-positive products. We have two additional patent applications in the U.S. and two applications in Europe relating to this technology. We are joint owner with Washington University of seven issued patents in the U.S. and two in Europe. In addition, there are four co-owned U.S. patent applications. These patents are for the technology used for the gram negative product opportunities. We are also the exclusive owner of one U.S. patent and one PCT application that relates to our DegP product opportunities.

The following is our patent position as of September 30, 2004:

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| PATENTS | Number Exclusively Licensed from Rockefeller Univ. | Number Co-Exclusively Licensed with Washington Univ. | Number Exclusively Licensed from Oregon State University | Number Exclusively Licensed from UCLA | Number Owned by SIGA |
|-------------------|--|--|--|---------------------------------------|----------------------|
| U.S. | 7 | 7 | 1 | | 1 |
| Australia | 5 | 2 | 1 | | |
| Canada | 3 | 1 | | | |
| Europe | 3 | 2 | | | |
| Japan | 4 | 2 | | | |
| Mexico | 1 | | | | |
| New Zealand | 1 | | | | |
| APPLICATIONS | | | | | |
| U.S. applications | 1 | 4 | | 1 | 3 |
| U.S. provisionals | | | | | 3 |
| Australia | 1 | | | 1 | 3 |
| China | 1 | | | | |
| Canada | 3 | 1 | 1 | 1 | 2 |
| Europe | 2 | | | 1 | 3 |
| Japan | 3 | | | 1 | 3 |

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We also rely on copyright protection, trade secrets, know-how, continuing technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of trade secrets and proprietary information, we require our employees, consultants and some collaborators to execute confidentiality and invention assignment agreements upon commencement of a relationship with us. These agreements may not provide meaningful protection for our trade secrets, confidential information or inventions in the event of unauthorized use or disclosure of such information, and adequate remedies may not exist in the event of such unauthorized use or disclosure.

We may have difficulty managing our growth.

We expect to experience growth in the number of our employees and the scope of our operations. This growth has placed, and may continue to place, a significant strain on our management and operations. Our ability to manage this growth will depend upon our ability to broaden our management team and our ability to attract, hire and retain skilled employees. Our success will also depend on the ability of our officers and key employees to continue to implement and improve our operational and other systems and to hire, train and manage our employees.

Our activities involve hazardous materials and may subject us to environmental regulatory liabilities.

Our biopharmaceutical research and development involves the controlled use of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for damages, and this liability could exceed our resources. The research and development activities of our company do not produce any unusual hazardous products. We do use small amounts of 32P, 35S and 3H, which are stored, used and disposed of in accordance with Nuclear Regulatory Commission ("NRC") regulations. We maintain liability insurance in the amount of approximately \$5,000,000 and we believe this should be sufficient to cover any contingent losses.

We believe that we are in compliance in all material respects with applicable environmental laws and regulations and currently do not expect to make material additional capital expenditures for environmental control facilities in the near term. However, we may have to incur significant costs to comply with current or future environmental laws and regulations.

Our potential products may not be acceptable in the market or eligible for third party reimbursement resulting in a negative impact on our future financial results.

Any products successfully developed by us or our collaborative partners may not achieve market acceptance. The antibiotic products which we are attempting to develop will compete with a number of well-established traditional antibiotic drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of our products will depend on a number of factors, including:

- o the establishment and demonstration in the medical community of the clinical efficacy and safety of such products,
- o the potential advantage of such products over existing treatment

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methods, and

- o reimbursement policies of government and third-party payors.

Physicians, patients or the medical community, in general, may not accept or utilize any products that we or our collaborative partners may develop. Our ability to receive revenues and income with respect to drugs, if any, developed through the use of our technology will depend, in part, upon the extent to which reimbursement for the cost of such drugs will be available from third-party payors, such as government

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health administration authorities, private healthcare insurers, health maintenance organizations, pharmacy benefits management companies and other organizations. Third-party payors are increasingly disputing the prices charged for pharmaceutical products. If third-party reimbursement was not available or sufficient to allow profitable price levels to be maintained for drugs developed by us or our collaborative partners, it could adversely affect our business.

If our products harm people, we may experience product liability claims that may not be covered by insurance.

We face an inherent business risk of exposure to potential product liability claims in the event that drugs we develop are alleged to cause adverse effects on patients. Such risk exists for products being tested in human clinical trials, as well as products that receive regulatory approval for commercial sale. We may seek to obtain product liability insurance with respect to drugs we and/or our collaborative partners develop. However, we may not be able to obtain such insurance. Even if such insurance is obtainable, it may not be available at a reasonable cost or in a sufficient amount to protect us against liability.

We may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market, which could harm sales of the affected products.

If we, or others, identify side effects after any of our products, if any, after they are on the market, or if manufacturing problems occur:

- o regulatory approval may be withdrawn;
- o reformulation of our products, additional clinical trials, changes in labeling of our products may be required;
- o changes to or re-approvals of our manufacturing facilities may be required;
- o sales of the affected products may drop significantly;
- o our reputation in the marketplace may suffer; and
- o lawsuits, including class action suits, may be brought against us.

Any of the above occurrences could harm or prevent sales of the affected products or could increase the costs and expenses of commercializing and marketing these products.

The manufacture of genetically engineered commensals is a time-consuming and complex process which may delay or prevent commercialization of our products, or

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may prevent our ability to produce an adequate volume for the successful commercialization of our products.

Although our management believes that we have the ability to acquire or produce quantities of genetically engineered commensals sufficient to support our present needs for research and our projected needs for our initial clinical development programs, management believes that improvements in our manufacturing technology will be required to enable us to meet the volume and cost requirements needed for certain commercial applications of commensal products. Products based on commensals have never been manufactured on a commercial scale. The manufacture of all of our products will be subject to current Good Manufacturing Practices, or "GMP," requirements prescribed by the FDA or other standards prescribed by the appropriate regulatory agency in the country of use. There can be no assurance that we will be able to manufacture products, or have products manufactured for us, in a timely fashion at acceptable quality and prices, that we or third party manufacturers can comply with GMP, or that we or third party manufacturers will be able to manufacture an adequate supply of product.

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Healthcare reform and controls on healthcare spending may limit the price we charge for any products and the amounts thereof that we can sell.

The U.S. federal government and private insurers have considered ways to change, and have changed, the manner in which healthcare services are provided in the U.S. Potential approaches and changes in recent years include controls on healthcare spending and the creation of large purchasing groups. In the future, the U.S. government may institute further controls and limits on Medicare and Medicaid spending. These controls and limits might affect the payments we could collect from sales of any products. Uncertainties regarding future healthcare reform and private market practices could adversely affect our ability to sell any products profitably in the U.S. At present, we do not foresee any changes in FDA regulatory policies that would adversely affect our development programs.

The future issuance of preferred stock may adversely affect the rights of the holders of our common stock.

Our certificate of incorporation allows our Board of Directors to issue up to 10,000,000 shares of preferred stock and to fix the voting powers, designations, preferences, rights and qualifications, limitations or restrictions of these shares without any further vote or action by the stockholders. The rights of the holders of common stock will be subject to, and could be adversely affected by, the rights of the holders of any preferred stock that we may issue in the future. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock, thereby delaying, deferring or preventing a change in control.

Concentration of ownership of our capital stock could delay or prevent change of control.

Our directors, executive officers and principal stockholders beneficially own a significant percentage of our common stock and preferred stock. They also have, through the exercise or conversion of certain securities, the right to acquire additional common stock. As a result, these stockholders, if acting together, have the ability to significantly influence the outcome of corporate actions requiring shareholder approval. Additionally, this concentration of ownership may have the effect of delaying or preventing a change in control of

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SIGA. At November 10, 2004, directors, officers and principal stockholders beneficially owned approximately 48.7% of our stock.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission. The prospectus relates to 1,000,000 shares of our common stock which the selling stockholders named in this prospectus may sell from time to time. We will not receive any of the proceeds from these sales. We have agreed to pay the expenses incurred in registering the shares, including legal and accounting fees.

The shares have not been registered under the securities laws of any state or other jurisdiction as of the date of this prospectus. Brokers or dealers should confirm the existence of an exemption from registration or effectuate such registration in connection with any offer and sale of the shares.

This prospectus describes certain risk factors that you should consider before purchasing the shares. See "Risk Factors" beginning on page 4. You should read this prospectus together with the additional information described under the heading "Where You Can Find More Information."

FORWARD-LOOKING STATEMENTS

This prospectus contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the efficacy of potential products, the timelines for bringing such products to market and the availability of funding sources for continued development of such products. Forward-looking statements are based on

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management's estimates, assumptions and projections, and are subject to uncertainties, many of which are beyond the control of SIGA, as well as assumptions made by and information currently available to management. When used in this prospectus, including the information incorporated by reference, the words "anticipate," "believe," "estimate," "expect," "may," "will," "continue" and "intend," and words or phrases of similar import, as they relate to our financial position, business strategy and plans, or objectives of management, are intended to identify forward-looking statements. Actual results may differ materially from those anticipated in any forward-looking statement. Factors that may cause such differences include the risks that (a) potential products that appear promising to SIGA or its collaborators cannot be shown to be efficacious or safe in subsequent pre-clinical or clinical trials, (b) SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products, (c) SIGA may not be able to obtain promised funding for its development projects or other needed funding, and (d) SIGA may not be able to secure or enforce adequate legal protection, including patent protection, for its products. More detailed information about SIGA and risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this presentation, is set forth under the heading "Risk Factors" beginning on page 4 of this prospectus, in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and in other documents that SIGA has filed with the Commission. SIGA urges investors and security holders to read those documents free of charge at the Commission's Web site at <http://www.sec.gov>. Interested parties may also obtain those documents free of charge from SIGA. SIGA does not undertake to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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Although we believe that our expectations are reasonable, we cannot assure you that our expectations will prove to be correct. Should any one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, actual results may vary materially from those described in this prospectus as anticipated, believed, estimated, expected, intended or planned.

USE OF PROCEEDS

The net proceeds from the sale of the shares of common stock offered will be received by the selling stockholders. We will not receive any of the proceeds from the sale of the shares of common stock offered by the selling stockholders.

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SELLING STOCKHOLDERS

The table below sets forth information regarding ownership of our common stock by the selling stockholders as of November 10, 2004, and the shares of common stock to be sold by them under this prospectus. Beneficial ownership is determined in accordance with rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Except as indicated by footnote, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. The rules of the Securities and Exchange Commission require that the number of shares of common stock outstanding used in calculating the percentage for each listed person includes the shares of common stock underlying warrants or options held by such person that are exercisable within 60 days of November 10, 2004. As of November 10, 2004, 24,500,648 shares of our common stock were outstanding.

| Name of Selling Stockholder | Securities Owned Prior to Offering | | Shares of Common Stock Offered Hereby | Securities to be Sold |
|-----------------------------|------------------------------------|-------------------------|---------------------------------------|-----------------------|
| | Shares of Common Stock | Percent of Common Stock | | |
| ViroPharma Incorporated | 700,000 | 2.9% | 700,000 | 700,000 |
| Marc Collett | 300,000 | 1.2% | 300,000 | 300,000 |

(1) Assumes that all shares of common stock covered by this prospectus are sold in the offering.

The information provided in the table above with respect to the selling stockholders has been obtained from such selling stockholders.

The selling stockholders have not within the past three years had any position, office or other material relationship with us or any of our predecessors or affiliates.

Because the selling stockholders may sell all or some portion of the shares of common stock beneficially owned by them, only an estimate (assuming the selling stockholders sell all of the shares offered hereby) can be given as to the number of shares of common stock that will be beneficially owned by the selling stockholders after this offering. In addition, the selling stockholders

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may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time or from time to time since the dates on which they provided the information regarding the shares beneficially owned by them, all or a portion of the shares beneficially owned by them in transactions exempt from the registration requirements of the Securities Act.

We have filed with the Securities and Exchange Commission, under the Securities Act of 1933, a registration statement on Form S-3, of which this prospectus forms a part, with respect to the resale of the securities from time to time on the Nasdaq SmallCap Market or in privately-negotiated transactions and have agreed to prepare and file such amendments and supplements to the registration statement as may be necessary to keep the registration statement effective until the earlier of (i) three years from the date on which this registration statement on Form S-3 becomes effective, or (ii) the date on which the selling stockholders have sold all of the shares of common stock.

PLAN OF DISTRIBUTION

This prospectus covers the sale of shares of common stock from time to time by the selling stockholders named in the table above and any of their pledgees, donees, assignees and successors-in-interest. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. The selling stockholders may effect such transactions by selling the shares to or through broker-dealers. The shares may be sold by one or more of, or a combination of, the following:

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- o a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker-dealer as principal and resale by such broker-dealer for its account pursuant to this prospectus;
- o an exchange distribution in accordance with the rules of such exchange;
- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- o in privately negotiated transactions;
- o broker-dealers may agree with selling stockholders to sell a specified number of such shares at a stipulated price per share; and
- o any other manner permitted pursuant to applicable law.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In effecting sales, broker-dealers engaged by the selling stockholder may arrange for other broker-dealers to participate in the resales.

The selling stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares in the course of hedging the positions they assume with the selling stockholders. The

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selling stockholders also may sell shares short and redeliver the shares to close out such short positions. The selling stockholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of the shares. The broker-dealer may then resell or otherwise transfer such shares pursuant to this prospectus.

Broker-dealers or agents may receive compensation in the form of commissions, discounts or concessions from the selling stockholders. Broker-dealers or agents may also receive compensation from the purchasers of the shares for whom they act as agents or to whom they sell as principals, or both. Compensation as to a particular broker-dealer might be in excess of customary commissions and will be in amounts to be negotiated in connection with the sale. Broker-dealers or agents and any other participating broker-dealers or the selling stockholders may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act in connection with sales of the shares. Accordingly, any such commission, discount or concession received by them and any profit on the resale of the shares purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act. Because the selling stockholders may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 promulgated under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling stockholders.

The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of such distribution. In

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addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our common stock by the selling stockholders. We will make copies of this prospectus available to the selling stockholders and have informed them of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of the shares.

We will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act upon being notified by the selling stockholders that any material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer. Such supplement will disclose:

- o the name of the selling stockholder and of the participating

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broker-dealer(s);

- o the number of shares involved;
- o the price at which such shares were sold;
- o the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable;
- o that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and
- o other facts material to the transaction.

We will bear all costs, expenses and fees in connection with the registration of the shares. The selling stockholders will bear all commissions and discounts, if any, attributable to the sales of the shares. We have agreed to indemnify certain selling stockholders against certain liabilities, including liabilities under the Securities Act in connection with the offering of the shares or to contribute to payments which such selling stockholders may be required to make in respect thereof. The selling stockholders may agree to indemnify certain persons, including broker-dealers and agents, against certain liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Kramer Levin Naftalis & Frankel LLP.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-KSB for the year ended December 31, 2003 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The financial statements of Plexus Vaccine Inc. incorporated in this prospectus by reference to Amendment No. 1 to the Current Report on Form 8-K dated May 23, 2003 (filed on July 22, 2003) have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

COMMISSION'S POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act

and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by one of our directors, officers or controlling persons in the successful defense of any action, suit or proceeding) is asserted by that director, officer or controlling person in connection with the securities being registered, we

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will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether that indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

ADDITIONAL INFORMATION

Government Filings.

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's web site at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's public reference room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the SEC's public reference room in Washington, D.C. by calling the SEC at 1-800-SEC-0330.

We have filed with the SEC a registration statement on form S-3 to register the shares of common stock to be offered. This prospectus is part of that registration statement and, as permitted by the SEC's rules, does not contain all the information included in the registration statement. For further information about us and our common stock, you should refer to that registration statement and to the exhibits and schedules filed as part of that registration statement, as well as the documents we have incorporated by reference which are discussed below. You can review and copy the registration statement, its exhibits and schedules, as well as the documents we have incorporated by reference, at the public reference facilities maintained by the SEC as described above. The registration statement, including its exhibits and schedules, are also available on the SEC's web site, given above.

Stock Market.

Shares of our common stock are traded on the Nasdaq SmallCap Market.

INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any further filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until this offering has been completed:

- o the Annual Report on Form 10-KSB for the year ended December 31, 2003;
- o the description of our common stock contained in our registration statement on Form 8-A under Section 12 of the Exchange Act, dated September 5, 1997, including any amendment or reports filed for the purpose of updating such description;
- o quarterly report on Form 10-QSB for the quarter ended March 31, 2004;
- o quarterly report on Form 10-QSB for the quarter ended June 30, 2004;
- o quarterly report on Form 10-QSB for the quarter ended September 30, 2004; and

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- o our current reports on Form 8-K filed on July 22, 2003, January 13, 2004, January 30, 2004, March 22, 2004, April 21, 2004, June 1, 2004, June 9, 2004, July 6, 2004, August 25, 2004

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(as amended on August 25, 2004), September 14, 2004, October 5, 2004, October 25, 2004 November 15, 2004 and November 24, 2004.

We will furnish to any person to whom this prospectus is delivered, without charge, a copy of these documents upon written or oral request to Thomas N. Konatich, Chief Financial Officer, 420 Lexington Avenue, Suite 601, New York, New York 10170, tel. (212) 672-9100.

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